## REMARKS

An Office Action was mailed in the above-captioned application on June 14, 2006. In such Office Action claims 1-38 were pending. Claims 1-38 were rejected. This Amendment and Remarks document is submitted in response to said Office Action. Claims 1-38 have been cancelled. New claims 39-80 are presented. Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

### Substance of Interview on November 16, 2006

Applicants appreciate the courtesy extended to them in receiving an interview with Examiner Haghighatian and Supervisory Patent Examiner Richter regarding the captioned application on November 16, 2006. The Office Action was discussed, including the proposed new claims submitted herewith. The Examiners indicated that the proposed new claims would distinguish the present invention over the prior art. Applicants agreed to file appropriate Terminal Disclaimers.

### The Amendments to the Claims

Without prejudice to the Applicants' rights to present claims of equal scope in a timely filed continuing application, in order to expedite prosecution and issuance of the application, the Applicants have cancelled claims 1-38 and added new claims 39-80.

The addition of new claims does not introduce new matter. Support for new claims 39-80 is found throughout the specification and in the original claims. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter and allow all claims.

### Claim Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-7, 22-24 and 33 under 35 U.S.C. § 112, first paragraph. Applicants submit that these rejections are moot in light of the amendments made herein, and respectfully request reconsideration of the rejection under 35 U.S.C. § 112, first paragraph, on this basis.

**Claim Rejections under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 2, 3, 9, 10, 13-16, 20, 21 and 24-32 under 35 U.S.C. § 112, second paragraph. Applicants submit that these rejections are moot in light of the amendments made herein, and respectfully request reconsideration of the rejection under 35 U.S.C. § 112, second paragraph, on this basis.

**Claim Rejections under 35 U.S.C. § 102**

The Examiner has rejected claims 8-16, 25-32 and 34-38 under 35 U.S.C. § 102(e) as being anticipated by Byron et al. (US 2004/0016427 A1). In support of this rejection, the Office Action states that Byron et al. discloses "a method and apparatus for generating an aerosol ... formed by supplying a material in liquid form to a tube and heating the tube such that the material volatizes and expands out of an open end of the tube." Office Action at 3. The Office Action goes on to state that the volatized material combines with ambient air such that the volatized material condenses to from the aerosol and that the aerosols are intended for inhalation and typically have a mass median particle size of less than 2 microns. *Id.*

In order to expedite the prosecution, Applicants have cancelled the pending claims and presented new claims 39-80. New independent claim 39 is directed to a composition for delivery of a drug comprising a condensation aerosol. In accordance with the invention, the condensation aerosol is formed by heating a thin film of a drug composition to produce a vapor, and condensing the vapor to form a condensation aerosol comprising the drug. The condensation aerosol comprises particles that are characterized by less than 10% drug degradation products by weight, wherein the condensation aerosol has an MMAD of less than 5 microns. Furthermore, the drug is a heat stable respiratory drug. New independent claim 67 is directed to a kit for delivering a condensation aerosol. In accordance with the invention, the kit comprises a thin film of a drug composition comprising a drug, on a solid support, and a device for providing the condensation aerosol. The condensation aerosol is formed by heating the drug compositing to produce a vapor, and condensing the vapor to form a condensation aerosol comprising the drug. The condensation aerosol comprises particles that are characterized

by less than 10% drug degradation products by weight, wherein the condensation aerosol has an MMAD of less than 5 microns. Furthermore, the drug is a heat stable respiratory drug.

Byron et al. fails to teach or disclose a thin film of a drug composition, or heating such a drug composition to produce a vapor. Furthermore, Byron et al. lacks specific disclosure of a heat stable drug or a condensation aerosol comprising particles characterized by less than 10% drug degradation products as those terms are used with respect to the present invention. *See, e.g.*, ¶ [0030] ("'Heat stable drug' refers to a drug that has a TSR $\geq 9$ when vaporized from a film of some thickness between 0.05 μm and 20 μm.").

Anticipation requires that "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industries. Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1642 (Fed. Cir. 1996), *see also* MPEP §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987). As Byron et al. fails to disclose a thin film of a heat stable drug composition, heating such a drug composition to produce a vapor, or obtaining a condensation aerosol comprising particles characterized by less than 10% drug degradation products by weight, the reference cannot be said to anticipate the composition of new claim 39 or the kit of new claim 67. As claims 40-66 depend from claim 39, and claims 68-80 depend from claim 72, these claims are not anticipated for the same reasons. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(e).

**Claim Rejections under 35 U.S.C. § 103**

The Examiner has rejected claims 1-7, 17-24 and 33 under 35 U.S.C. § 103 as being unpatentable over Byron et al. in view of Bartus et al. (US 6,514,482). Office Action at 4. In support of this rejection, the Office Action states that Byron et al. "lacks specific disclosure on [a] method of treating ailments," but that Bartus et al. "teaches a method of pulmonary delivery of a medicament which includes administering … particles …, where the particles preferably have an aerodynamic diameter between about 1 and 5 μm." *Id.* (emphasis omitted). The Office Action further states that Bartus et al.

discloses medicaments containing from 1 to about 90 weight percent of drugs, including anti-inflammatory agents, muscle relaxants, apomorphine, acetaminophen, lidocaine, diazepam, etc., that are delivered via a dry powder inhaler, metered dose inhaler, nebulizer or instillation techniques. *Id.* at 4-5.

The Office Action states that it "would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the method of treating ailments and medicaments of Bartus et al. in the aerosol device of Byron et al. for delivering the aerosolized compositions to a subject's respiratory tract." *Id.* at 5.

Applicants respectfully disagree in view of the elements of the proposed new claims and the disclosures of Byron et al. and Bartus et al.

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations." Obviousness cannot be established by combining teachings in the prior art, absent some teaching or suggestion in the prior art that the combination be made (*In re Stencel* 828 F. 2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987); *In re Newell* 891 F. 2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989)).

One of skill in the art would not have a reasonable expectation that the device of Byron et al. would successfully form condensation aerosols suitable for inhalation that are characterized by less than 10% drug degradation products and an MMAD of less than 5 microns from the compositions of Bartus et al. For instance, under the method of Byron et al, the medicament compositions of Bartus et al. ("solid component") would have to be put into liquid form by combining with a "liquid component." Byron et al. at ¶ [0076]. However, Byron et al. fails to provide specific guidelines for selecting an appropriate "liquid component" for a given medicament composition ("solid component") or for predicting what effect heating the mixture will have on the solid component. This is further complicated when the medicament composition contains one

or more additional components, such as the surfactants, phospholipids, amino acids, etc., taught in Bartus et al. Bartus et al., col. 8, line 42 to col. 11, line 53.

Moreover, these references do not teach or suggest all of the elements of independent claims 39 or 67. Neither Byron et al. nor Bartus et al. teaches or discloses a thin film of a heat stable drug composition, or heating such a drug composition to produce a vapor. Furthermore, like Byron et al., Bartus et al. lacks specific disclosure of a condensation aerosol comprising particles characterized by less than 10% drug degradation products as those terms are used with respect to the present invention.

Thus, these references singly or in combination do not teach or suggest all the claim elements. Accordingly, the Office Action fails to establish even a *prima facie* case of obviousness. Moreover, for the same reasons, there would be no motivation to combine the references to achieve the presently claimed invention, nor is it seen how the combination of the references would achieve the presently claimed invention. Claims 40-66 which depend from claim 39 are not obvious for the same reasons as claim 39. Claims 68-80 which depend from claim 67 are not obvious for the same reasons as claim 67.

Finally, the Examiner has rejected claims 1-38 under 35 U.S.C. § 103 as being unpatentable over Faithfull et al. (US 6,041,777) in view of Bartus et al. In support of this rejection, the Office Action states that Faithfull et al. teaches methods and apparatus for closed-circuit ventilation therapy, including the use of nebulizers to provide fluorochemicals and/or pharmaceutical agents, heated above body temperature, to a ventilating gas in the form of a vapor and that this is accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. Office Action at 6. The Office Action also states that Faithful et al. discloses that the method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors. *Id.*

The Office Action states that Faithfull et al. lacks "disclosure on medicaments and methods of treating" but that Bartus et al. "discloses a wide variety of therapeutic agents suitable for aerosol delivery to one's respiratory system." *Id.* The Office Action asserts that it "would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the method and apparatus for ventilation therapy as

taught by Faithfull by adding the method of treating and wide variety of medicaments suitable for aerosol delivery as taught by Bartus, because of the disclosed benefits of such a method, including minimized trauma to the lungs and a better resolution of pulmonary and systemic disorders, and because of the need to treat a wide variety of diseases." *Id.* at 6-7.

Applicants respectfully disagree in view of the elements of the proposed new claims and the disclosures of Bartus et al. and Faithfull et al. Bartus et al. fails to teach or disclose a condensation aerosol. Rather Bartus et al. is directed to a method of delivering low tap density particles for the treatment of CNS disorders and in particular, Parkinson's disease, via dry power inhalers or metered dose inhalers. Nowhere does Bartus et al. disclose or suggest condensing a vapor to form a condensation aerosol comprising a drug, nor the advantages obtained by such a condensate aerosol. Additionally, Bartus et al. lacks teachings on heating the drug composition. Dry powder inhalers, metered dose inhalers, nebulizers or instillation techniques do not vaporize the drug and then form a condensate of the drug. Additionally, in Bartus et al. there is no disclosure of how one would form such a condensation aerosol comprising an antiparkinsonian drug or any other drug compound to generate an aerosol comprising particles characterized by less than 10% drug degradation products by weight, or how to obtain aerosols having a MMAD of less than 5 microns when heating a drug composition to produce a vapor and condensing the vapor. Nor does Bartus et al. disclose a thin layer of a heat stable drug composition. These elements, which are not taught in Bartus et al., are required by new independent claims 39 and 67.

Faithfull et al. does not cure these deficiencies or make obvious in view of Bartus et al. how to accomplish these tasks. Faithfull et al. does not disclose or teach a condensation aerosol as defined by the Applicants' claims (or any condensation aerosol for that matter) or how to make such an aerosol. Faithfull et al. discloses the use of a warmed fluorochemical as a solvent for delivering the active compound "oxygen" to the lungs of the patient using a ventilation system. The active or therapeutic compound or drug in Faithfull et al. is not heated to produce a vapor or condensed to form a condensation aerosol comprising particles, as is set forth in new independent claims 39 and 67 of the present application. Instead, Faithfull et al. requires the use of a wetted

surface or wick to get the fluorochemical (solvent) to form a droplet. Moreover, as is stated in the Office Action, the fluorochemical in Faithfull et al., unlike the present invention, is being delivered to the lung as a vapor and not an aerosol. See Office Action at 6 ("As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces" (emphasis added)). Faithfull et al. does not disclose how to make a condensation aerosol comprising particles characterized by less than 10% drug degradation products by weight, or how to obtain a condensation aerosol having an MMAD of less than 5 microns. Nor does Faithfull et al. teach or disclose a thin film of a heat stable drug composition, or heating such a drug composition to produce a vapor.

The Office Action also suggests that "condensates" by their nature have a high percentage of purity of the drug and less degradation products. Applicants respectfully disagree. The mere fact that an aerosol is formed by condensation does not mean that the aerosol will have a high percentage of drug and less degradation products.

Faithfull et al. does not cure the deficiencies of Bartus et al. Accordingly, the Office Action fails to establish even a *prima facie* case of obviousness as each and every element of the invention is not taught or disclosed by these references. Moreover, there would be no motivation to combine the references to achieve the presently claimed invention. Even if the cited references were combined, the claimed invention would not result because neither Bartus et al. nor Faithfull et al. is directed to a thin film of a drug composition comprising a drug, on a solid support, or heating such a drug composition to produce a vapor, or to forming condensation aerosols comprising particles characterized by less than 10% drug degradation products and an MMAD of less than 5 microns. Claims 40-66 which depend from claim 39 are not obvious for the same reasons as claim 39. Claims 68-80 which depend from claim 67 are not obvious for the same reasons as claim 67.

Accordingly, and in light of the foregoing arguments, the Applicants respectfully submit that these amendments put the case in condition for allowance and request that the Examiner reconsider and withdraw all rejections based on 35 U.S.C §103.

**Double Patenting Rejections**

Claims 1-38 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,716,415; 6,716,416; 6,716,417; 6,737,042; 6,737,043; 6,740,307; 6,740,308; 6,740,309; 6,743,415; 6,759,029; 6,776,978; 6,780,399; 6,780,400; 6,783,753; 6,797,259; 6,803,031; 6,805,853; 6,805,854; 6,814,955; 6,855,310; 7,052,680; 7,052,679; 7,048,909; 7,045,119; 7,045,118; 7,03,575; 7,029,658; 7,022,312; 7,018,621 and 7,018,620 as these claims are "either anticipated by, or would have been obvious over, the reference claims."

Also, claims 1-38 were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. (Publication document Nos.) 2003138382; 20030206869; 20040009128; 20040096402; 20040099266; 2004099269; 20040101481; 20040105818; 20040105819; 20040126326; 20040126327; 20040126328; 20040126329; 20040127481; 20040127490; 20040156788; 20040156789; 20040156790; 20040156791; 2004161385; 20040167228; 20040170569; 20040170570; 20040170571; 20040170572; 20040170573; 20040171609; 20040184996; 20040184997; 20040184998; 20040184999; 20040185000; 20040185001; 20040185002; 20040185003; 20040185004; 20040185005; 20040185006; 20040185007; 20040185008; 20040186130; 20040191179; 20040191180; 20040191181; 20040191182; 20040191183; 20040191184; 20040191185; 20040202617 and 20040228807 and Application Nos. 10/749,537; 10/749,539; 10/718,982; 10/749,783; 10/768,205; 10/146,516; 10/912,462; 10/146,516; 10/150,056; 10/150,267; 10/150,268; 10/150,591; 10/150,857; 10/151,596; 10/151,626; 10/152,639; 10/152,640; 10/152,652; 10/153,139; 10/153,311; 10/153,313; 10/153,831; 10/153,839; 10/154,594; 10/154,765; 10/155,097; 10/155,373; 10/155,621; 10/155,703; 10/155,705; 10/280,315; 10/302,010; 10/302,614; and 10/322,227. *Id.* at 8-9.

Applicants agree to file appropriate terminal disclaimers when the claims are otherwise in condition for allowance.

Applicants believe that this addresses the Examiner's concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of these actions and remarks.

**Closing Remarks**

The Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. The Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues, prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date 12/14/06

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